

CLAIMS

1. A spore genetically modified with genetic code comprising at least
2 one genetic construct encoding an antigen and a spore coat protein as a
chimeric gene, said genetically modified spore having said antigen
4 expressed as a fusion protein with said spore coat protein.
2. A spore as claimed in Claim 1 characterised in that the spore is of
2 *Bacillus* species.
3. A spore as claimed in Claim 1 or Claim 2 characterised in that the
2 genetic construct comprises at least part of a spore coat protein gene and at
least part of an antigen gene, in the form of a chimeric gene.
4. A spore as claimed in any one of the preceding Claims characterised
2 in that the antigen gene is located at the 3' end of the spore coat protein
gene.
5. A spore as claimed in any one of the preceding Claims characterised
2 in that the genetic construct comprises a spore coat promoter at the 5' end
of the chimeric gene.
6. A spore as claimed in any one of the preceding Claims characterised
2 in that the antigen is at least one of tetanus toxin fragment C or labile toxin
B subunit.
7. A spore as claimed in any one of the preceding Claims characterised
2 in that the spore coat protein is selected from the group consisting of *cotA*,
cotB, *cotC*, *cotD*, *cotE*, *cotF*, *cotG*, *cotH*, *cotJA*, *cotJC*, *cotM*, *cotSA*, *cotS*,
4 *cotT*, *cotV*, *cotW*, *cotX*, *cotY* and *cotZ*.

8. A spore as claimed in any one of the preceding Claims characterised
2 in that the spore is heat inactivated that in use it does not germinate into a vegetative cell.
9. A spore as defined in any one of the preceding Claims for use in
2 treatment of a medical condition.
10. A composition comprising at least two different spores as defined in
2 any one of the preceding Claims characterised in that said at least two different spores express at least two different antigens.
11. A composition as defined in Claim 10 characterised in that the
2 composition further comprises a pharmaceutically acceptable excipient or carrier.
12. A composition comprising a spore as defined in any one of claims 1
2 to 9 in association with a pharmaceutically acceptable excipient or carrier.
13. A composition as defined in any one of Claims 10 to 12 for use in
2 treatment of a medical condition, preferably the medical condition is inflammation, pain, a hormonal imbalance and/or an intestinal disorder.
14. Use of a spore as defined in any one of claims 1 to 9 in the
2 manufacture of a medicament for use in the treatment of a medical condition, preferably the medical condition is inflammation, pain, a
4 hormonal imbalance and/or an intestinal disorder.

15. A method of medical treatment, which method comprises the steps
2 of
- a) administering a spore as defined in any one of claims 1 to 9 to
4 a human or animal in need of medical treatment;
 - b) said genetically modified spore eliciting an immune response
6 for use in the prevention of a disease.
16. A method as claimed in Claim 15 characterised in that the spore is
2 administered orally, intra-nasally or rectally.
17. A method of producing a genetically modified spore, which method
2 comprises the steps;
- producing genetic code comprising at least one genetic construct
4 encoding an antigen and a spore coat protein as a chimeric gene;
 - 6 using said at least one genetic construct to transform a vegetative
mother cell;
 - 8 inducing said transformed mother cell to sporulate; and
 - 10 isolating the resulting genetically modified spores.